



CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1307

[Docket No. CPSC-2014-0033]

Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates

AGENCY: Consumer Product Safety Commission.

ACTION: Request for comments.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is publishing this document following a Federal court opinion remanding the Commission's final phthalates rule to allow the Commission to address two procedural deficiencies found by the court. This document seeks public comment regarding the justification for the phthalates final rule and the staff's cost-benefit analysis for continuing the interim prohibition on DINP.

DATES: Written comments should be submitted by [insert date that is 45 days from publication of this notice in the Federal Register].

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2014-0033, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (e-mail), except through <https://www.regulations.gov> and as described below. The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/hand delivery/courier Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7479. Alternatively, as a temporary option during the COVID-19 pandemic, you can email such submissions to: cpsc-os@cpsc.gov.

Instructions: All submissions received must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. Do not submit electronically confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for written submissions.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, and insert the docket number, CPSC-2014-0033, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Susan Proper, Directorate for Economic Analysis, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7628; email: sproper@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 108(b)(3) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) required the Commission to promulgate a final rule addressing children’s toys and child care articles containing certain phthalates not later than 180 days after the Commission received a final Chronic Hazard Advisory Panel (CHAP) report.¹ The Commission was required to “determine, based on such report, whether to continue in effect the [interim] prohibition” on children’s toys that can be placed in a child’s mouth and child care articles “in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.” 15 U.S.C. 2057c (b)(3)(A). Additionally, the Commission was required to “evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children’s product containing any phthalates to be a banned hazardous

¹ The Commission voted 4–0 to approve this notice.

product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children.” 15 U.S.C. 2057c (b)(3)(B).

On December 30, 2014, the Commission published a notice of proposed rulemaking (NPRM) in the *Federal Register*. 79 FR 78324. The Commission published a final rule on October 27, 2017, with an effective date of April 25, 2018. 82 FR 49938. The final rule was substantially the same as the proposed rule. The preambles of the NPRM and final rule provide more detailed discussions of the CHAP report and staff’s technical analysis and findings in support of the rule.

In December 2017, the Texas Association of Manufacturers and others petitioned the U.S. Court of Appeals for the Fifth Circuit for a review of the CPSC’s final phthalates rule. In March 2021, the court remanded without vacating the phthalates final rule to the CPSC to address two procedural deficiencies found by the court. *Tex. Ass’n of Mfrs. v. United States Consumer Prod. Safety Comm’n*, 989 F.3d 368 (5th Cir. 2021). As relevant here, the court held that the final rule had failed to: (1) provide adequate notice and comment regarding a change in the primary justification from the proposed rule to the final rule; and (2) consider the costs and benefits of continuing the interim prohibition on DINP. This document is being published to address these two procedural deficiencies. We note that the court did not vacate the final rule, and thus the rule remains in effect.

II. Request for Comments

A. Phthalates Final Rule Justification

The Fifth Circuit held that the phthalates final rule did not provide adequate notice and comment regarding a change in the primary justification between the proposed rule and the final rule. The court remanded the rule to allow CPSC to seek public comment on the justification for the final rule. The Commission’s justification for the proposed rule was based on data demonstrating that 10 percent of pregnant women had a Hazard Index (HI) greater than one, which exceeded the acceptable risk, and that the average HI was five at the 95th percentile. *See*

79 FR 78328-32. The Commission's justification for the proposed rule was based on available data showing that a statistically stable, non-zero percentage of the women studied had an HI greater than one and that an HI less than or equal to one is necessary "to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety." *See* 79 FR 78334-35.

After publication of the proposed rule, the Commission examined new data using the CHAP's original methodology. Based on the new data, the Commission determined that phthalate exposures had changed over time and that there were too few samples in the study with an HI above one to make a statistically reliable estimate for the population of the number or percentage of women of reproductive age with an HI greater than one. No new data on infants were available, so risk estimates for this population did not change in the updated analysis. Based on the new data for women of reproductive age, the Commission found that the risk of antiandrogenic effects had decreased, and that the HI at the 95th percentile had decreased from five to less than one. 82 FR 49958. Based on the new data, the Commission could not determine exactly what percentage of the women studied had an HI greater than one but did state that "between two and nine real women from the sample of 538 [women of reproductive age] had an HI greater than one." *Id.* The Commission's justification for the final rule was based on the facts that between two and nine individual samples had HI levels greater than one and not the 10 percent of women who had exposures described in the proposed rule, and that no new data on infants were available. For details regarding the respective justifications, potential commenters are directed to the preamble of the respective *Federal Register* notices for the proposed and final rule.

The court of appeals held that the Commission did not provide adequate notice and comment when it changed the justification for the prohibitions in the proposed rule to the final rule. Accordingly, the Commission is publishing this notice to request public comment regarding the justification for the final rule.

B. Request for Comment on Cost-Benefit Analysis of

Continuing Interim DINP Prohibition

The Fifth Circuit held that the final phthalates rule was deficient because it did not consider the costs and benefits of continuing the interim prohibition on DINP. Specifically, the court found that the Commission was required at least to consider the cost, as well as the effect on utility and availability of products containing DINP, to determine whether to continue the interim prohibition.

The staff of the Directorate for Economic Analysis has conducted a cost-benefit analysis regarding continuing the interim prohibition on DINP in the final rule. The staff memorandum “Cost-Benefit Analysis of Continuing the Interim DINP Prohibition in the Final Rule: 16 CFR part 1307 ‘Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates’” can be found here. https://www.cpsc.gov/s3fs-public/CostBenefitAnalysisDINPinPhthalatesFinalRule.pdf?VersionId=4dQErAhY2cQdvQpf1I8rAqTNCjinie_h. The Commission requests public comment regarding the cost-benefit analysis of continuing the interim prohibition on DINP in the final rule.

III. Submission of Comments

We request comments on two issues: the rationale for the final rule in section II.A; and the cost-benefit analysis of continuing the DINP interim prohibition discussed in section II.B of this document. Only comments submitted regarding the rationale for the final rule and/or the cost-benefit analysis of continuing the DINP interim prohibition will be considered. Comments submitted on any other issues are out of scope and will not be considered. Finally, untimely submitted comments will not be considered.

Information regarding the court decision is available on the CPSC website or <http://www.regulations.gov>, under Docket No. CPSC-2014-0033, Supporting and Related Materials. Alternatively, interested parties may obtain a copy of the court decision by writing or

calling the Division of the Secretariat, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-6833.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

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